



ENVIRONMENTAL LAW FOUNDATION

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December 3, 2018

Via Electronic Submission

Monet Vela
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Re: Environmental Law Foundation Comments on Proposed Amendments to Cal Code Regs. tit. 27, section 25821(a) and (c), Calculating Exposure by the Average Consumer of a Product

Dear Ms. Vela:

Environmental Law Foundation writes today to support the proposed amendments to California Code of Regulations, title 27, section 25821 (a) and (c).

Section 25821(a)

The amendments to section 25821(a) prevent a troubling method that defendants in Proposition 65 cases use to avoid responsibility for warning Californians of an exposure to a listed chemical in food: averaging concentrations of a chemical across lots. The proposed action will limit the use of this method and will protect Californians from receiving unwarned exposures.

Under current law, courts have permitted defendants to calculate the “level in question” of a chemical in a given product by averaging the concentrations of chemicals across several units of that product. In some cases, courts have allowed defendants to include samples in the average from different production lots.¹

This methodology presents a problem. We have experience with situations in which companies source the raw ingredients for their products from different regions and even different countries. This may be due to a number of factors, including variations in

¹ See *Environmental Law Foundation v. Beech-Nut Nutrition Corp.* (2015) 235 Cal.App.4th 307, 323-27 (*Beech-Nut*). Environmental Law Foundation was the plaintiff in this case.

growing seasons across the globe and fluctuations in pricing. And many companies use several different production facilities to process and package their products. Pollution in one particular region or contamination at one particular plant can therefore cause products to contain chemicals at a level that requires warning in certain lots, but not others. Thus some lots of a product may contain high levels of a chemical, while other lots contain none at all.

Under current law, defendants may include clean products alongside products containing a listed chemical when calculating the level in question. This practice unfairly dilutes the sample, potentially masking real exposures, as *Beech-Nut* demonstrates. Exposures to listed chemicals in problematic lots are real, and Californians are entitled to a warning before consuming those products. The fact that an entirely different lot may contain lower levels of a chemical is simply not relevant when a consumer eats a food that contains a chemical at a level that requires a warning.

OEHHA's proposed amendment is an important step towards solving this issue.

Section 25821(c)

The proposed amendments to Section 25821(c) also address an important issue: prohibiting the use of the geometric mean to understate rates of intake or exposure.

Under current law, there is limited guidance for calculating rates of intake or exposure. Courts have thus far allowed defendants to use the geometric mean to calculate the rate of exposure. (See *Beech-Nut*, 235 Cal.App.4th at 316, 325-27.) It is a law of statistics that using the geometric mean will necessarily result in a lower calculated average than using the arithmetic mean.² This is because the geometric mean places relatively lower emphasis on the highest values in the sample. And the more variable the sample, the more the geometric mean underemphasizes the higher values.

Importantly, in a sample of food consumers, those who consume the most food are at the highest risk from consuming listed chemicals. Because the arithmetic mean places more appropriate weight on those higher exposures, it is the more appropriate measure. OEHHA is therefore correct to require the use of the arithmetic mean.

Conclusion

For the forgoing reasons, ELF supports the proposed regulations. In the coming months, we also hope to see OEHHA propose regulations that tackle other lingering issues in Proposition 65 enforcement. One such issue would be the logical next step of

² The only exception is if all data points in the sample have exactly the same value. (*Id.* at 325, fn.7.)

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addressing inappropriate use of averaging over time for exposures to teratogenic chemicals.

Sincerely,

A handwritten signature in black ink, appearing to read "Nathaniel H. Kane". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Nathaniel Kane
Staff Attorney
Environmental Law Foundation